

**BEUC's comments on the draft working paper for a Commission Directive on infant formulae and follow-on formulae (SANCO D4/HL/mm/D440180 Rev.2)**

**INTRODUCTION**

BEUC<sup>1</sup>, the European Consumers' Organisation, welcomes the opportunity to comment on the draft working paper, SANCO D4/HL/mm/D440180 Rev.2, for a Commission Directive on infant formulae and follow-on formulae, and is pleased to provide the following comments.

This review is timely and welcome in view of the enlargement of the European Commission and the need to ensure the optimum protection of infant and young child health through the protection of breastfeeding throughout the Community and globally.

We are also pleased that the directive maintains the nutritional needs as the basis for the nutritional composition of both infant formulae and follow-on formulae. It is extremely important to have an all-inclusive directive to ensure the protection of all infants.

We welcome the revision of Commission Directive 91/321/EEC of 14 May 1991, and ask that it takes into consideration:

- Discussions with Member States;
- The most recent scientific findings of the Scientific Committee on Food on the Revision of Essential Requirements of Infant Formulae and Follow-on Formulae;
- Discussions at the international level within the Codex Alimentarius Forum.
- Resolutions passed at the World Health Assembly.

In general, BEUC welcomes the intention of the draft legislation to review and update:

- The definition of infant formulae and follow-on formulae;
- The inclusion of new ingredients;
- Labelling provisions and claims;
- Essential composition of infant formulae and follow-on formulae

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<sup>1</sup> BEUC acts on behalf of 38 independent national consumer organisations from 28 European countries.

- Reference values for nutritional labelling.

After analyses of the working document it seems to us that the following aspects need particular consideration, of which some are in the remit of our experiences and expertise, while some others might need additional expert review.

## Recital 2

*“The essential composition of infant formulae and follow-on formulae must satisfy the nutritional requirements of infants in good health as established by generally accepted scientific data.”*

Comment:

“Infant in good health as established by generally accepted scientific data” might give room for interpretation, since the term ‘in good health’ is not defined.

We therefore suggest to use the terminology “**healthy infant**” as used in the report of the Scientific Committee on Food on the Revision of Essential Requirements of Infant Formulae and Follow-on Formulae, or the removal of the term altogether as suggested by some health organisations.

## Recital 3

Comment:

Soya protein is mentioned as a regular ingredient of infant formulae and follow-on formulae. It is important to draw the Commission’s attention to the fact that the use of **soya protein** has been questioned by at least two scientific bodies, both the UK Committee on Toxicity (COT) and the Scientific Advisory Committee on Nutrition (SACN) on Phytoestrogens and Health (<http://www.food.gov.uk>)<sup>2</sup>

We understand that at the last Experts the safety of phytoestrogens in soya-based formulas was raised by Member States along with a proposal for stronger labelling for such formulas. BEUC would support this proposal.

## Recital 6

Comment:

It is stated that microbiological criteria and maximum levels of contaminants should be set at a later stage because of the complexity of the issue.

However, in the light of the recent outcome of the discussion in the Joint FAO/WHO Workshop on *Enterobacter sakazakii*, the discussion in the Codex Committee for Food Hygiene and the EFSA opinion related to microbiological risks in infant formulae and follow-on formulae<sup>3</sup>, we believe it is important to begin considering microbiological criteria immediately.

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<sup>2</sup> The SACN report states: “ 20.... SACN is in agreement that the use of soy-based infant formulae is of concern. Whilst there is clear evidence of potential risk, there is no evidence that these products confer any health benefit or therapeutic advantage over products based on cow’s milk protein isolates....there are no substantive medical or clinical indications for the use of soy-based formulae and, secondly on grounds of potentially important sequelae, principally amongst young infants. If the use of soy-based formula is to continue on “clinical” grounds, responsibility is placed upon health professionals rather than the industry and consumers. “

<sup>3</sup> [http://www.efsa.eu.int/press\\_room/press\\_release/696\\_en.html](http://www.efsa.eu.int/press_room/press_release/696_en.html): EFSA Panel advises on how to avoid microbiological risks in infant formulae – at home and in hospital

## Recital 8

Comment:

Reference is made to various directives dealing with pesticides. However, we find it important that the same rules as applied for cereal-based baby food for infants and young children and suggested therefore to include references to these directives.

1. Commission Directive 2003/13/EC of 10 February 2003 amending Directive 96/5/EC on processed cereal-based foods and baby foods for infants and young children; and
2. Commission directive 1999/39/EC of 6 May 1999 amending Directive 96/5/EC on processed cereal-based foods and baby foods for infants and young children.

## Recital 19

*“During the first months of life”*

Comment:

This term *“During the first months of life”* is not specified further. Therefore, it is necessary to introduce a time frame here and we believe this should be six months to bring the draft legislation in line with The WHA Resolution 54.2 2002<sup>4</sup>

## Recital 24

After the wording *“International Code of Marketing of Breast-Milk Substitutes adopted by the 34th World Health Assembly”* add **“and subsequent relevant World Health Assembly Resolutions”**, and delete the subsequent remaining part of the recital **“bearing in mind...in the Community”**.

Comment:

Since the 34<sup>th</sup> WHA 10 WHA resolutions on infant feeding have been adopted, with the support of all EU Member States. These Resolutions have the same legal status as the International Code and should therefore be included here and taken into consideration in the text as appropriate.

## Articles 2(c) and 3

*“During the first months of life”*

Comment:

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<sup>4</sup> World Health Assembly in 2002 “to strengthen activities and develop new approaches to protect, promote and support exclusive breastfeeding for six months as a global public health recommendation, taking into account the findings of the WHO expert consultation on optimal duration of exclusive breastfeeding”

As in recital 19 this term is not specified further. Therefore, it is necessary to introduce a time frame here and we believe this should be 6 months to bring the draft legislation in line with The WHA Resolution 54.2 2002

#### **Article 4**

In relation to the composition of the formulas reference is made to “**generally accepted scientific data**”.

Comment:

We find it important that generally accepted scientific data is defined and it must be made clear that these data should come from independent research.

#### **Article 4(2)**

*“When an infant formula containing an ingredient which has not been used in the manufacture of infant formula before [xxx], is placed on the market for the first time the manufacturer ... shall notify the competent authority of the Member State where the product is being marketed by forwarding it a model of the label used for the product.”*

Comment:

The article gives the impression that new ingredients may be introduced into these formulae through a simple process. We strongly believe that this approach is far too liberal. Compared to the novel food procedure it might even give the impression that the Community cares less about infant food than it does about other foods.

We find it important that new ingredients having a particular nutritional property in both infant and follow-on formulae should be permitted only if their safety or expressed benefit has been conclusively demonstrated through independent scientific evaluation and authorisation prior to market introduction. The EFSA should be involved in this evaluation, unless otherwise suggested by independent scientific advice. However, such ingredients, if proven to be essential and safe for infant health, should be considered legally required ingredients and mentioned in the positive lists of annex III.

For many children infant formula and follow-on formulae is their only nutritional source in a long and important period of their life and must be safe.

#### **Article 7(7)**

We suggest that his article should read “**Microbiological criteria shall be determined as soon as possible**” or words to that meaning.

#### **Article 8(5)(b)**

We suggest inserting the word ‘**independent**’ before the word ‘professional’ to read:

*“a statement recommending that the product be used only on the advice of independent persons having qualifications in medicine, nutrition or pharmacy, or other **independent** professionals responsible for maternal and child care.”*

## **Article 8(7)**

Comment:

We are concerned about the rather liberal approach in relation to nutrition and health claims in Annex IV and recommend that the Annex is removed.

In 1995 the European Commission issued a discussion paper for Member States about whether health claims should be permitted. The paper clearly showed that from the industry's perspective health claims have far more to do with providing benefits for the producer than informing the consumer.<sup>5</sup> It stated: *“... [The claim] would allow the company to gain a competitive advantage and allow it to recover its investment in research.”*

Moreover, concerns about claims are also expressed in the report of the Scientific Committee on Food on the Revision of Essential Requirements of Infant Formulae and Follow-on Formulae of 4 April 2003. Health and nutrition claims on breast milk substitutes are intended to idealise products to create a perceived advantage and are not the same as the provision of clear and comprehensive nutrition information which of course BEUC strongly recommends. Breast milk (and breastfeeding) is not packaged and promoted in the same way so is inevitably disadvantaged by any thing which idealises breastmilk substitutes.

There can be no health advantage in using breast milk substitutes over breastfeeding since artificial feeding increases mortality rates, increases rates for illnesses such as infectious diseases, chronic diseases and auto-immune diseases, offers less than optimal development and growth, lowers cognitive and visual development and increases the risk of obesity

Health and nutrition claims violate the International Code of Marketing of Breast-milk Substitutes and the subsequent relevant World Health Assembly Resolutions and should not be permitted as it could be detrimental to breast feeding<sup>6</sup>.

Parents and health professionals should be confident that any infant formulae on sale in the European Union will be made to the highest possible standard, and that its ingredients are those that are legally required and in line current scientific knowledge. Not many consumers are qualified to see through possible claims. On top of this, claims regarding optional ingredients allow for "parallel marketing", i.e. so-called journalistic descriptions which can exaggerate and distort the importance of the ingredients, misleading the purchaser and undermining breastfeeding and infant health.

## **Additional subparagraph to Article 8**

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<sup>5</sup> Claims for infant formulae, European Commission DG III paper, 27 March 1995. III/5185/95-EN iii.E.1-BM/cvi

<sup>6</sup> The Danish Consumer Council support the claim "lactose free", but nothing beside that. All other claims concern ingredients for which no minimum levels are applied, and therefore no recommendations. The Lactose free statement is important for a small number of infants, which will be under close medical supervision. This statement should appear clearly in the nutrition panel.

With reference to the EFSA Panel advice on how to avoid microbiological risks in infant formulae at home and in hospital, and because of Salmonella and *Enterobacter sakazakii* being the micro-organisms of greatest concern in these formulae, we suggest to add the following statements on the label:

- a statement concerning the hazards of incorrect preparation<sup>7</sup>; and
- a statement that this product is not sterile.

### **Article 9(1)**

We suggest changing this sentence to read: ***“Advertising of infant formula and follow-on formula and other forms of promotion, including by electronic means is prohibited.”***

### **Insert New Article 9(4)**

We suggest adding this addition sentence ***“Marketing personnel, in their business capacity, should not seek direct or indirect contact of any kind with parents, parents to be or carers of infants and young children.”***

Comment:

This is consistent with Article 5 of the International Code

### **Article 10(2)**

In the last sentence insert the words ***‘or text’*** after ‘pictures’ to read: ***“Such materials should not use any pictures or text which may idealise the use of breast milk substitutes.”***

Comment:

This ensures that the text is consistent with Article 4.2 of the International Code.

### **Article 10(4)**

We suggest a change in the text to read: ***“Member States shall ensure that free and low-cost supplies of breast milk substitutes should not be allowed in any part of the health care system.”***

Comment:

This ensures that the text is consistent with subsequent WHA Resolutions, specifically WHA 47.5 adopted in 1994.

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<sup>7</sup> Our Italian member, Altroconsumo, suggests adding a clear indications on how to prepare correctly the infant formulae, before a statement on the hazards of incorrect preparation, which is already present on the products sold in Italy. Furthermore, in order to avoid the risk related to *E. sakazakii*, infant formulae should be prepared at a temperature of 70°C. This should be clearly indicated, but the indications available at present on the labels refer to temperatures included between 40-50°C

## **Annex I and II**

In the light of our concerns expressed under recital 3 we find it important that EFSA gives an opinion on the suitability of soya in infant formulae and follow-on formulae

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